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A prospective randomised trial of four-layer *versus* short stretch compression bandages for the treatment of venous leg ulcers

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This trial was undertaken to examine the safety and efficacy of four-layer compared with short stretch compression bandages for the treatment of venous leg ulcers within the confines of a prospective, randomised, ethically approved trial.

Fifty-three patients were recruited from a dedicated venous ulcer assessment clinic and their individual ulcerated limbs were randomised to receive either a four-layer bandage (FLB) (n=32) or a short stretch bandage (SSB) (n=32).

The endpoint was a completely healed ulcer. However, if after 12 weeks of compression therapy no healing had been achieved, that limb was withdrawn from the study and deemed to have failed to heal with the prescribed bandage. Leg volume was measured using the multiple disc model at the first bandaging visit, 4 weeks later, and on ulcer healing. Complications arising during the study were recorded. Data from all limbs were analysed on an intention to treat basis; thus the three limbs not completing the protocol were included in the analysis.

Of the 53 patients, 50 completed the protocol. At 1 year the healing rate was FLB 55% and SSB 57% (χ^2 =0.0, df=1, P=1.0). Limbs in the FLB arm of the study sustained one minor complication, whereas SSB limbs sustained four significant complications. Leg volumes reduced significantly after 4 weeks of compression, but subsequent volume changes were insignificant. Ulcer healing rates were not influenced by the presence of deep venous reflux, post-thrombotic deep vein changes nor by ulcer duration. Although larger ulcers took longer to heal, the overall healing rates for large (>10 cm^2) and small (10 cm^2 or less) ulcers were comparable.

Four-layer and short stretch bandages were equally efficacious in healing venous ulcers independent of pattern of venous reflux, ulcer area or duration. FLB limbs sustained fewer complications than SSB.

Venous ulceration places a significant burden on National Health Service resources. In the United Kingdom, at any one time approximately 100 000 people have a venous ulcer *(1)*, each ulcer costing £2000–£4000 per annum to treat *(2)*, the cost of venous ulceration to the NHS has been estimated to be £150–£600million per annum *(3)*. It is therefore imperative to ensure that each patient is offered appropriate and optimal treatment. Compression bandaging is the established method of treatment for venous ulcers and two frequently used bandage systems are the short stretch and four-layer regimens. Initial non-randomised uncontrolled trials reported by Blair *et al. (4)* and Moffatt *et al. (5)* suggested that approximately three-quarters of ulcerated limbs would heal by 12 weeks using the four-layer system. Duby *et al. (6)* compared four-layer and short stretch bandages in a prospective randomised manner and found healing rates of 44% and 40%, respectively, at 12 weeks. Thus, from the available evidence it remains unclear which of the two commonly used compression bandages, short stretch or four-layer, is

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more efficacious. In order to address this clinically and economically important issue we report the results of a prospective randomised trial comparing four-layer and short stretch compression bandages.

Patients and methods

Patients

Patients with active lower limb ulceration were identified from those attending a venous ulcer assessment clinic at which each limb underwent a full assessment as previously described *(7)*. Ulcers were identified as venous if the only demonstrable abnormality was venous reflux of >0.5 s duration and an ankle brachial pressure index (ABPI) of >0.8.

Study design

The study was designed to examine the safety and efficacy of four-layer (FLB) and short stretch (SSB) compression bandages when used to heal venous ulcers in a prospective, randomised manner with the approval of the local ethical committee. Limb randomisation was performed at the first attendance for bandaging and was achieved using sealed envelopes naming the type of bandage to be applied determined by a block randomisation method *(8)*; in addition, limbs were stratified within each arm of the trial by initial ulcer area into two groups: 10 cm^2 or less and over 10 cm^2. Patients with bilateral disease had each ulcerated limb randomised separately; thus, it was possible for a single patient to be prescribed different bandages for each leg. The type of bandage remained unchanged until the ulcers had healed. However, if by 12 weeks there was no evidence of ulcer healing or the ulcers deteriorated within that time then that limb was deemed to have failed to have healed with the allocated bandage and was withdrawn from the trial. After withdrawal, the alternative bandage was applied in an attempt to achieve ulcer healing. At the initial hospital visit for commencement of bandaging, the size of each ulcer was measured and leg volume recorded. This was repeated every 2 weeks until that individual limb had completed the trial protocol or had been withdrawn.

Colour duplex scanning

A colour duplex scan of the deep and superficial veins was performed at the assessment clinic visit to define venous anatomy and function, with particular reference to the pattern of venous reflux in each limb. Venous reflux was defined as the presence of reversed blood flow for more than 0.5 s on release of a calf squeeze distal to the segment of vein under examination. The superficial venous system was defined as the saphenous veins, their tributaries and the perforating veins; the deep venous system included any vein deep to but not traversing the lower limb deep fascia. Evidence of previous deep vein thrombosis (DVT) was inferred from the following features on duplex scanning: old intraluminal thrombus (incompressible vein), thickened and/or scarred vein walls, stenosis of the vein and shrunken and scarred valve cusps.

Ulcer area

Ulcer areas were obtained by computerised planimetry of tracings of the ulcer perimeter made onto transparent acetate sheets taken at the time of first bandaging attendance and at 2-weekly intervals thereafter. Ulcer healing was determined by inspection and deemed to be complete if full re-epithelialisation had occurred.

Leg volume

Leg volume was calculated using the 'multiple disc model' *(9,10)*. The limb circumference was measured (in centimeters) at 4 cm intervals from the tip of the medial maleolus to the tibial tuberosity. Where the tibial tuberosity fell between measurement points the final disc circumference was recorded at the closest point distal to the tuberosity. The volume is calculated thus:

$$\sum_{i=1}^{n} \frac{C_i^2}{\pi}$$

where C is the circumference corresponding to each 4 cm interval and n the number of 4 cm segments (this will vary in proportion to the limb length). Volumes were calculated from measurements taken at 2-weekly intervals at the time of bandage changes with the patient in a supine position. The 4 cm intervals were marked on the skin, and the same investigator (JMS) performed the measurements to ensure a comparable technique was used throughout the study period.

Bandages and dressings

A standardised method of ulcer dressing was adopted throughout the study period and was carried out by trained nursing staff with a number of years experience in the techniques of compression bandaging, thus ensuring reproducible bandage application for the duration of the study period. The primary dressing throughout the study period consisted of simple non-adherent NA dressings (Johnson & Johnson Ltd, UK) *(11)* followed by a layer of sterile gauze. The compression bandages were applied on top of this as follows. The FLB was applied in the standard manner *(5,12)*, defined by the ankle circumference and consisted of Velband® (Johnson & Johnson), Crêpe, Elset® (Seton) and Coban® (3M). The SSB was Rosidal K® (Lohmann) and was applied in accordance with the manufacturer's recommendations of 50% stretch with 50% overlap between turns. A minimum of two layers of wool (Velband) was applied around the ankle and along the tibial crest to protect these bony prominences from local pressure effects. Unfortunately, our experience with this bandage before the start of the trial found it necessary to apply a cohesive retaining layer overlying the Rosidal K in order to prevent it from slipping down towards the ankle rendering it ineffective as a compression

bandage. This layer was in the form of Coban applied without any stretch such that its contribution to the overall compression was minimal while ensuring retention of the Rosidal K. Compression pressure was measured as the sub-bandage pressure using a Talley II Oxford Pressure Monitor (Talley Group Ltd, UK). A small flat plastic 'envelope' is located between the bandage and the primary dressing and the attached tubing brought to the bandage surface by a suitable route between the bandage layers. The free end of the tubing is connected to the Oxford Pressure Monitor. Pressure readings were taken 20 min after application of the bandage components (to allow the bandage to settle on the leg) at a point 4 cm proximal to the medial maleolus, representing the sub-bandage pressure at the ankle. Data collected during an as yet unpublished study found the median (range) increase in sub-bandage pressure at the ankle caused by the additional layer of Coban was 11.5 mmHg (range −1 to 18 mmHg). Bandages were changed once weekly, or occasionally more frequently if clinically indicated by excessive exudate and bandage soiling. The FLB was replaced with all new components at each visit, whereas patients in the SSB arm of the trial were supplied with two Rosidal K, one to be used and the other washed by the patient for use at the next bandage change. The bandages were replaced after 20 washings. Once healed, the limb was measured by an orthotist and a Class II below-knee compression stocking was fitted.

Analysis of data

Ulcerated limbs were analysed on an intention to treat basis and efficacy was determined for each of the two trial arms. Data were analysed using non-parametric statistics as appropriate. The two arms of the trial were directly compared using the Mann–Whitney *U* statistic, and healing rates were examined in the form of Kaplan–Meier plots comparing trial arms with the log rank test. Data from the two trial arms were combined and the following factors were examined using χ^2 for an association with complete ulcer healing: initial ulcer area >10 cm^2, ulcer duration >6 months, evidence of a previous DVT, and the presence of deep venous reflux. The computer software Statistical Package for Social Sciences (SPSS, Chertsey, UK) was used for the analysis.

Results

Randomisation

Fifty-three patients (64 ulcerated limbs) were randomised to receive either FLB or SSB. Of these patients, 20 were male and the median (range) age for all 53 patients was 73 years (range 36–93 years). Forty-two patients had unilateral ulcers (26 left leg and 16 right) randomised thus, FLB 22 limbs and SSB 20 limbs. Eleven patients had bilateral ulcers randomised as follows: FLB to one leg and SSB to the other, seven patients; SSB to both legs, two patients and FLB to both legs two patients. Thus, of the 64 ulcerated limbs, 32 were allocated FLB and 32 SSB. The proportion of limbs with initial ulcer areas >10 cm^2 in each arm of the trial was as follows: FLB 21/32 and SSB 14/32 (χ^2 =2.20, df=1, P=0.14.

During the study period, one patient died after two attendances and two patients repeatedly failed to attend and ultimately defaulted from follow-up to the community nursing service. These two patients represented two ulcerated limbs randomised FLB one limb and SSB one limb. They were subsequently considered as treatment failures and are thus included in the analysis of results on an intention to treat basis.

The characteristics of the two trial arms are detailed in Table I. The two groups were comparable for each of the features examined.

Ulcer healing

Overall ulcer healing rates for each arm (SSB and FLB) of the trial are shown in the form of a Kaplan–Meier plot (Fig. 1). The ulcer healing rate at 1 year was 55% for the FLB group and 57% for the SSB group, Log Rank analysis found no difference in efficacy ($\chi^2=0.0$, df=1, P=1.0).

Since both bandages demonstrated equal efficacy, data from the two arms of the trial were combined and the following characteristics were examined for any influence on complete ulcer healing: initial area >10 cm^2, duration of ulcer >6 months, duplex evidence of previous DVT, presence of deep venous reflux. These data are outlined in Table II. None of the above-mentioned factors showed an association with complete ulcer healing.

Table I. Details of the two arms of the trial

	Short stretch limb (n=32)	*Four-layer limb (n=32)*	*Significance level (P)*
Age (years)	73 (36–93)	70 (45–91)	0.34†
Initial ulcer area (cm^2)	8.3 (2–104)	13.3 (2–378)	0.05†
Number of limbs with ulcers >10 cm^2	14	21	0.14*
Ulcer duration (months)	21 (3–360)	13 (1–480)	0.47†
Initial ankle circumference (cm)	25.3 (26–32)	24.5 (20–32)	0.29†
Initial limb volume (L)	2.75 (1.37–4.22)	2.44 (1.40–4.48)	0.16†

Values are reported as median (range) * χ^2 = 2.20, df=1 † Mann–Whitney *U* test

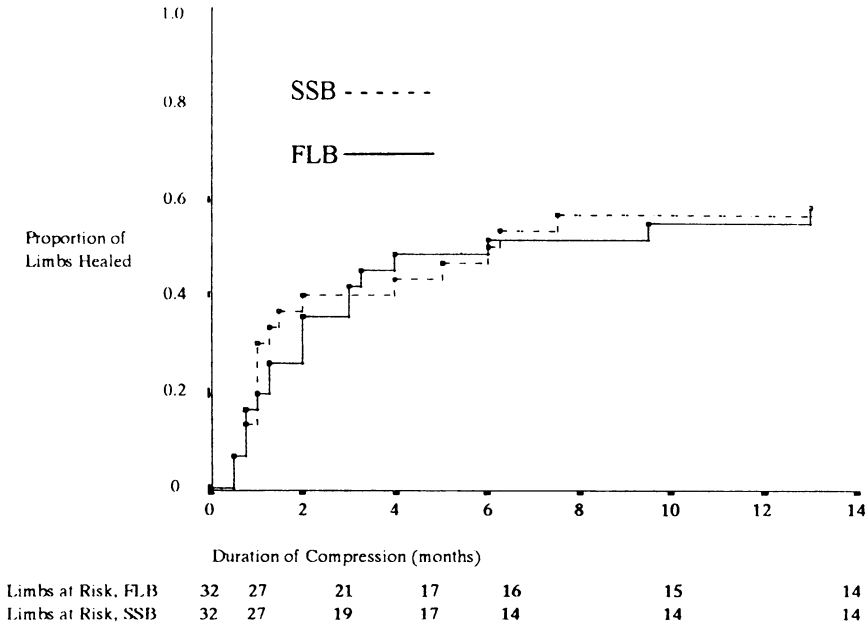

Figure 1. Kaplan–Meier plot of ulcer healing by bandage. FLB = Four-layer bandage, SSB = short stretch bandage. For all data points the standard error is < 10%.

Table II. Influence of initial ulcer area, ulcer duration, previous DVT and deep venous reflux on complete ulcer healing. For each characteristic one degree of freedom exists. Data from both arms of the study combined

	FLB and SSB combined	χ^2	*P*
Ulcer area >10 cm^2	17/35 (49%)	1.17	0.28
<10 cm^2	18/29 (62%)		
Ulcer duration >6 months	27/47 (57%)	0.27	0.60
<6 months	8/17 (47%)		
Evidence of previous DVT	8/11 (72%)	1.74	0.19
No evidence of previous DVT	27/53 (51%)		
Deep venous reflux	15/31 (48%)	0.96	0.33
No deep venous reflux	20/33 (61%)		

Effect of compression on leg volume

Leg volumes in each of the trial arms at the initial visit, 4 weeks after starting bandaging and the percentage reduction in volume at 4 weeks are shown in Table III. We found that both bandages dispersed oedema to an equal degree.

Complications

Of the 32 limbs randomised to receive four-layer bandages, only one limb (3%) sustained any complication. This consisted of minor haemorrhagic blistering of the toes distal to the bandage which fully resolved without sequelae. The initial ankle circumference in this case was 25 cm.

Of the 32 limbs receiving short stretch bandages, four limbs (13%) sustained clinically significant complications as follows: exposure of tibialis anterior tendon at the level of the ankle joint crease (ankle circumference 21.8 cm) and one limb experienced necrosis of the heel in association with patchy necrosis of the skin overlying the tibial crest (ankle circumference 20 cm), these limbs

Table III. Leg volumes at first attendance, 4 weeks later and the percentage reduction in volume after 4 weeks of compression therapy

	SSB	*FLB*
Vol 0 (L)	2.75 (1.37–4.22)	2.44 (1.40–4.48)
Vol 4 weeks (L)	2.33 (1.31–4.24)	1.92 (1.33–3.47)
Percentage reduction (%)	13.1* (73.4 to −1.4)	8.8* (48.2 to −53.1)

Values are expressed as median (range). * P=0.34 (Mann–Whitney U test)

were two of the thinnest of all limbs studied. Two further limbs suffered significant skin maceration (ankle circumferences 24.5 cm and 29 cm), one of these limbs was the most oedematous in the SSB arm.

Discussion

The optimal non-surgical treatment of chronic venous ulceration is graduated compression bandaging *(13)* rather than a non-compressive bandaging such as a paste-based bandage. The most efficacious compression bandage has not yet been identified.

This study compared the efficacy of two compression bandages, FLB and SSB, in a prospective, randomised, stratified manner. The endpoint of a completely healed ulcer was chosen to eliminate the potential difficulty of interpreting rates of wound closure for ulcers of varying contour. Although methods have been described to standardise the rate of advancement of a wound edge *(14)*, a healed wound is a definitive and incontrovertible endpoint. The components and method of application of the FLB have been previously described *(4)*. However, in this study the SSB (Rosidal K) required an additional layer of Coban as a retaining layer. Without this extra retaining layer the SSB failed to remain in place on the leg for 7 days. Others have also found maintaining an SSB in position difficult without recourse to an extra retaining layer *(6)*. The Coban described in this instance was applied without tension to minimise any additive compressive force. Although we found an increase in compression of 11.5 mmHg due to the Coban this could only act to enhance the compression rather than detract from it, we therefore feel that this does not alter the validity of our findings.

The characteristics of the two arms of the trial are comparable (Table I), although the median ulcer area was slightly larger in the FLB arm. This is explained by the broad range of ulcer areas included in the study and that no upper limit of ulcer area was enforced as an exclusion criterion. Furthermore, the study was stratified by initial ulcer area into two groups: 10 cm^2 or less, and >10 cm^2; examining the proportions of ulcers in each study limb we confirmed an even distribution of ulcers size across the two study arms. It is noteworthy that the median areas reported here exceed those appearing elsewhere in the literature *(4,5)*; moreover, others have reported mean ulcer areas *(6,15)* which will give the impression of larger ulcers having been studied. In this report the mean ulcer areas were as follows: FLB 49.6 cm^2 and SSB 19.1 cm^2 misleadingly exaggerating ulcer size because of the range in ulcer areas recruited to the study. It is possible that the ulcer dimensions seen in our ulcer clinics are greater than those in the community as many patients referred for a vascular surgical opinion may be a select group by nature of their reluctant ulcer healing and hence stage of disease. However, this is a minor source of bias towards more difficult ulcers as indicated by the range of both initial ulcer areas (2–378 cm^2) and ulcer duration (1–480 months) reported here.

We found no significant difference in the ability of either bandage to heal ulcers. Stratifying by ulcer area demonstrated no greater ability for FLB over SSB to successfully heal large or small ulcers. In view of this, clinicians and patients can be encouraged that even large ulcers can be treated successfully by adequate outpatient compression bandaging.

Although efficacy was not dependent on the bandage type, we found four significant complications in the SSB arm and one minor complication in the FLB arm. Interestingly, the most serious complications occurred in the SSB arm and involved pressure-induced iatrogenic ulceration in non-oedematous limbs with small ankle circumferences and significant maceration in limbs with larger, more oedematous legs. In fact, the iatrogenic ulceration occurred in two of the three smallest limbs studied and one of the macerated limbs was the most oedematous in the study. We saw no such pressure-induced complications in the small limbs in the FLB group; likewise, maceration was less problematic in oedematous limbs treated with FLB. This is most likely related to the composition of the bandages. Short stretch bandages having fewer layers will exhibit a reduced absorptive capacity when compared with FLB, hence the increased maceration as leaking tissue fluid will be held in contact with the non-ulcerated surrounding skin rather than being drawn into the bandage, keeping the skin relatively dry. Similarly, having fewer layers seems to enhance any local pressure effects despite the recommended wool padding giving rise to more iatrogenic ulceration. Four-layer bandages on the other hand exert a more evenly distributed pressure profile *(16)*, reducing iatrogenic ulceration in small limbs and the extra layer of crêpe and complete layer of wool seemed to absorb tissue fluid resulting in absence of severe maceration in this study arm.

Limb volumes were obtained indirectly from the summation of 4 cm deep discs between two fixed points (medial maleolus and tibial tuberosity). Water displacement techniques are considered to be the 'gold standard' method *(10)*, but this would be impractical for the often elderly patients with ulceration who are of limited mobility. Leg volumes behaved as expected, ie most of the oedema was dispersed in the initial month of bandaging; this period corresponds to the period during which legs can appear to exude larger quantities of fluid. Once the excess tissue fluid has being either absorbed into the circulation (compression increases the extravascular hydrostatic pressure) or lost via the ulcer base into the bandages, subsequent leg volumes changed little and the leg volume at healing was similar to that after 1 month of compression. The two concerns of patients experiencing this fluid loss into the bandage was the odour associated with the wet bandage, which disappeared on removal of the bandage where the ulcer itself was not found to be malodorous, in addition the exudate coagulated in the bandage causing it to set hard like a plaster cast in a small number of cases. These two factors were pivotal in deciding to change the bandages twice weekly rather than once per week.

In comparing two treatments, the cost of each is becoming an increasingly important and influential factor in prescribing. The cost of all components in the four-layer bandage used here obtained from a High Street retail pharmacy was £15.10, and assuming that each limb is bandaged once per week and takes 26 weeks to heal, the total cost of bandages is £392.60. Considering the short stretch bandage priced from the same pharmacy, two short stretch bandages were supplied at the initial visit and changed after 20 washes, these two bandages would therefore last for 40 weeks. Changing the short stretch bandage weekly only required replacement dressings, wool and Coban, thus this regimen costs £7.10, and over a 6 month period the cost is £184.56. These calculations take no account of the hidden costs such as ambulance transport to and from the hospital and staff salaries, but for the purpose of comparing costs of two bandages these can largely be ignored as these costs are common to both arms of the study. However, despite the inference that SSBs are cheaper than FLBs, the cost of treating any ensuing complications must be borne in mind. In this study we report two major and two lesser complications in legs treated with SSBs. Obviously, the management of such complications will probably offset any financial gains resulting from the use of a cheaper bandage technique.

In summary, this paper describes the efficacy of short stretch and four-layer compression bandages used to treat venous ulceration. Both bandages were found to be equally effective, but the SSB required external support by a retaining layer of cohesive bandage and was associated with complications in limbs with dimensions at the extremes of those studied.

References

1 Callum MJ, Ruckley CV, Harper DR, Dale JJ. Chronic ulceration of the leg: extent of the problem and provision of care. *BMJ* 1985; **290**: 1855–6.

2 Bosanquet N. Costs of venous ulcers: from maintenance therapy to investment programmes. *Phlebology* 1992; **Suppl 1**: 44–6.

3 Wilson E. Prevention and treatment of venous leg ulcers. *Health Trends* 1989; **21**: 97

4 Blair S, Wright D, Backhouse C, Riddle E, McCollum C. Sustained compression and healing of chronic venous ulcers. *BMJ* 1988; **297**: 1159–61.

5 Moffatt CJ, Franks PJ, Oldroyd M *et al.* Community clinics for leg ulcers and impact on healing. *BMJ* 1992; **305**: 1389–92.

6 Duby T, Hoffman D, Cameron J, Doblhoff-Brown D, Cherry G, Ryan T. A randomized trial in the treatment of venous leg ulcers comparing short stretch bandages, four-layer bandage system, and a long stretch-paste bandage system. *Wounds* 1993; **5**: 276–9.

7 Scriven JM, Hartshorne T, Thrush AJ, Bell PRF, Naylor AR, London NJM. A single visit venous ulcer assessment clinic: the first year. *Br J Surg* 1997; **84**: 334–6.

8 Altman DG. Designing research. In: Anonymous. *Practical Statistics for Medical Research.* London: Chapman & Hall, 1996: 74–106.

9 Badger C. Guidelines for the calculation of limb volume based on surface measurements. *Br Lymphol Int Grp Newsletter* 1993; **7**: 3–7.

10 Tierney S, Aslam M, Rennie K, Grace P. Infrared optoelectronic volumetry, the ideal way to measure limb volume. *Eur J Vasc Surg* 1996; **12**: 412–17.

11 Blair SD, Backhouse CM, Wright DDI, Riddle E, McCollum CN. Do dressings influence the healing of chronic venous ulcers? *Phlebology* 1988; **3**: 129–34.

12 Freak L, McCollum CN. The effective management of venous ulceration. *Vasc Med Rev* 1992; **3**: 53–62.

13 Ruckley CV. Treatment of venous ulceration—compression therapy. *Phlebology* 1992; **Suppl 1**: 22–6.

14 Gilman TH. Parameter for measurement of wound closure. *Wounds* 1990; **3**: 95–101.

15 Charles H. Compression healing of ulcers. *J Dist Nursing* 1991; **Sept**: 4–8.

16 Callum MJ, Haiart D, Farouk M, Brown D, Prescott RJ, Ruckley CV. Effect of time and posture on pressure profiles obtained by three different types of compression. *Phlebology* 1991; **6**: 79–84.

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